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10/625,202	07/23/2003	Carl Gustav Figdor	ALXN-P02-089	1242
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EXAMINER HILL, MYRON G				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/625,202
Filing Date: July 23, 2003
Appellant(s): FIGDOR *ET AL.*

Ryan Murphy
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/5/10 appealing from the Office actions mailed 10/6/09 and 1/5/10.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1, 3, 4, 6, 7, 19, and 23-27.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of

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rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS."

New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

Grijtenbeek, T.B.H., Identification of DC-SIGN, a Novel Dendritic Cell-Specific ICAM-3 Receptor that Supports Primary Immune Responses. *Cell*, Vol. 108 (3 March 21000), pages 575-585.

Steinbrook, R., One Step Forward, Two Steps Back- Will There Ever Be an AIDS Vaccine, *New England Journal of Medicine*, Vol. 357 (2007) pages 2653-2655.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4, 6, 7, 19, and 23-27 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a

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way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention is drawn to reducing T-cell mediated immune responses by administering an antibody that binds SEQ ID #2.

The post filing art, Geijtenbeek Cell Vol. 100 page 575-585, from IDS 7/31/06, shows that not all antibodies that bind the sequence have the same function (Figure 2).

Specification provides no guidance or direction or teaching on specific regions the antibody binds to, or what the variants of the sequence are that can function and give rise to antibodies that have the same function.

The specification only teaches AZN-D1 and D2 in *in vitro* assays.

Also, the physiological art in general is acknowledged as unpredictable (MPEP 2164.03).

The enabling disclosure is clearly not commensurate in scope with these claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Without specific guidance or direction and /or working examples, one of ordinary skill in the art would not be able to reproducibly practice the claimed invention without undue experimentation.

(10) Response to Argument

Appellant presents three main sections of arguments.

In section A, appellant argues that the examiner has not met the burden for establishing a prima facie case of lack of enablement. Appellant argues that *in vivo* results are not required to show *in vivo* use and that *in vitro* results are generally predictive of *in vivo* results.

Appellant's argument should not be found persuasive because appellant's assertions do not support the invention claimed.

Appellant argues that Ingulli *et al.*, Steinman, and Pereira *et al.* provide *in vitro* to *in vivo* correlation. The references have been discussed previously and show results or correlation with activating T-cells or increasing immune response, not the method claimed.

Appellant's argument that Ingulli *et al.* show correlation has been previously discussed and should not found to be persuasive because the teachings of Ingulli *et al.* show lymph nodes are removed to study cell interaction. There is no showing of any immune response (Non-Final Rejection mailed 3/6/09, page 5).

Appellant's argument that Steinman show correlation has been previously discussed and should not found to be persuasive because the teachings of Steinman teach that DC and T-cell interaction induce an immune response, not the reduced immune response as now claimed (Final Rejection mailed 10/6/09, pages 3 and 4).

Appellant's argument that Pereira *et al.* teach *in vitro* effect is predictive of *in vivo* should not be found persuasive because the teachings of Pereira *et al.* show they use antigen bound to antibody which is not required in the present claims and teach that AZN-D1 antibodies effectively induces an immune response (page 713, column 2, near top) which is opposite the claimed invention (Final Rejection mailed 10/6/09, pages 3 and 4).

Appellant's arguments concerning MPEP 2464 and type of molecule are not persuasive because MPEP 2164.03 provides the basis for doubt (In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. In re Fisher, 427F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) MPEP 2164.03 near end). The level of skill in antibody binding to antigen is well known (appellant refers to exquisite specificity) but the claims require reducing a T-cell mediated immune response. The evidence provided by appellant, discussed above, while providing evidence that dendritic cells and T-cells interact does not show a reduced immune response. The teachings of Ingulli *et al.*, Steinman, and Pereira *et al.* show that interaction induces an immune response.

In section **B**, appellant argues that the method of decreasing an immune response is differentiated by distinct method steps.

Appellant's argument has should not be found persuasive because the method steps are not differentiated as asserted by appellant.

Appellant asserts the use of naked antibody differentiates the method. The claims do not recite the limitation naked antibody. The claims do not differentiate the two inventions or embodiments as argued by appellant. The evidence provided by appellant as discussed above points to activating T-cells or inducing an immune response, not reducing an immune as the claims recite.

As indicated in the in the action mailed 3/6/09 (pages 4 and 5), appellant has tried to differentiate the claimed method by adding "in need thereof" (citing *Jansen v Rexall*) and the use of the term is not analogous to the pending claims. The claims from the cited case recite a condition, anemia, and a cause, a deficiency in folic acid or vitamin B12, in a method of treating a patient in need thereof. The pending claims give no such guidance in defining the population by providing a specific included group but only include "not infected with HIV" as the intended population.

In section C, appellant argues and asserts that the specification teaches the significance of the claimed method amount and type of immune response and concludes that one of skill in the art would have known what to expect from the *in vitro* examples and known the significance of the invention *in vivo*.

Appellant's argument should not be found persuasive because appellant's arguments as to the disclosure are not commensurate with the invention claimed.

The specification provides no teaching of the amount or type of reduced immune response or what the significance is *in vivo* or what that level of reducing produces as indicated in the action mailed 1/5/10. While the specification

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contemplates the invention with reducing immune responses and the examiner does not doubt the specificity of antibody binding, the claims are drawn to a method that requires reducing an immune response. The disclosure asserts the antibody can induce or reduce an immune response. The evidence provided by appellant shows an increased immune response (discussed above).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/M. G. H./

Examiner, Art Unit 1648

Conferees:

/Zachariah Lucas/

Supervisory Patent Examiner, Art Unit 1648

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649